

EXHIBIT 16

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN THE MATTER OF)	
)	
IN RE BAIR HUGGER FORCED AIR)	
WARMING)	
PRODUCTS LIABILITY LITIGATION)	
)	
Plaintiff,)	
)	PRETRIAL ORDER NO: 7
v.)	Protective Order
)	MDL No. 15-2666
3M COMPANY AND ARIZANT)	(JNE/FLN)
HEALTHCARE INC.)	
Defendant.)	

DEPOSITION OF PAUL MCGOVERN

VOLUME II

Thursday, January 5, 2017

AT: FAEGRE BAKER DANIELS LLP

Taken at:

7 Pilgrim Street

London EC4V 6LB

United Kingdom

Court Reporter:

Louise Pepper: Accredited Real-time Reporter

Videographer: Simon Addinsell

JOB NO. 117121

1
2
3 **A P P E A R A N C E S**

4 Appearing for the Plaintiff:

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13 Appearing for the Defendant:

14 **MR. COREY GORDON**
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17 **Minneapolis, MN 55415**

18 **MS. KATHERINE NEWMAN**
19 **FAEGRE BAKER DANIELS**
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21 Appearing for the Witness:

22 **MR. ANDREW HEAD**
23 **MR. BRYAN SHACKLADY**
24 **FORSTERS**
25 **31 Hill Street**
London W1J 5LS

1
2 Exhibit 9 Document entitled "Do324
3 Forced Air Warming Devices
4 Increase Bacterial
5 Contamination of Operative
6 Field? - Simulated experiment
7 analysis".

8 Exhibit 10 Email chain between336
9 Paul McGovern and Val
10 Edwards-Jones "Re Saturday",
11 dated 26 November - 20
12 December 2009

13 Exhibit 11 Email chain between337
14 Paul McGovern, David Leaper,
15 Andrew Sprowson and Thomas
16 Symes, "Prof David Leaper
17 Visit", dated 10 September - 2
18 December 2009

19 Exhibit 12 Email chain between342
20 Paul McGovern and Mike Reed,
21 dated 21 February 2010,
22 "Laminar flow tests".

23 Exhibit 13 Article co-published by347
24 Paul McGovern and others,
25 entitled "Forced-air warming
and ultra-clean ventilation do
not mix." Bates stamped
Belani_000190-000197

Exhibit 14 Article entitled353
"Patient Warming Excess Heat:
The Effects on Orthopedic
Operating Room Ventilatio
Performance", Bates stamped
Belani_000040-000045

Exhibit 15 Email chain between359
Mark Albrecht, Paul McGovern
and others, dated 1 February
2011, "Manuscript with updated
joint infection data covering
an additional 200 or so".

Exhibit 16 Excel spreadsheet with365
data analysis

1
2 **W I T N E S S I N D E X**

3 Examination by MR. SACCHET239

4 Examination by MR. C. GORDON459

5 **E X H I B I T I N D E X**

6 Exhibit 1 Email chain between P.263

McGovern and M. Albrecht,

7 Bates stamped Albrecht_0016487

8 Exhibit 2 Email chain between Mark287

Albrecht, Paul McGovern, Mike

9 Reed and others, dated 30 June

to 3 July, 2010

10 Exhibit 3 Forced Air Warming289

Demonstration DVD

11 Exhibit 4 CDC document entitled298

"Healthcare Infection Control

12 Practices Advisory Committee

Record of the Proceedings",

13 dated November 5-6, 2015,

14 previously marked as Exhibit

208, Bates stamped

3MBH01344612-01344685

15 Exhibit 5 Document entitled306

"Forced Air Warming (FAW) and

16 Surgical Site Contamination

First Draft" dated 27/9/09

17 Exhibit 6 Document entitled "Do308

Forced Air Warming Devices

18 Increase Bacterial

Contamination of Operative

20 Field? - Simulated

21 experimental analysis".

22 Exhibit 7 Email chain dated 8-11309

November, 2009, subject line:

23 "FAW"

24 Exhibit 8 Document Bates stamped316

3MBH00107863-00107870

1
2 Exhibit 17 Email chain between372

Mark Albrecht, Mike Reed, Paul

3 McGovern and others, dated 18

4 February - 1 March 2011,

"Signatures on Transmittal

5 Letter".

6 Exhibit 18 Email chain between373

Paul McGovern and Mark

7 Albrecht, dated 19 May - 23

8 May, 2011, "Fwd: JBJS [BR] log

No. 27124 - Invitation to

resubmit

9 Exhibit 19 Email chain "Re382

McGovern" between Robin

10 Humble, Scott Augustine, Paul

11 McGovern and others plus

12 attachment entitled "Observed

reduction in periprosthetic

13 joint infections: Antibiotics

or warming technique?", dated

25 March - 17 June 2016.

14 Exhibit 20 Journal of Bone and391

Joint Surgery document

15 entitled "Wound Complications

Following Rivaroxaban

Administration".

16 Exhibit 21 Paper entitled "Return396

to theatre following total hip

17 and knee replacement, before

18 and after the introduction of

rivaroxaban".

19 Exhibit 22 Journal of403

Tissueviability paper entitled

20 "A prospective randomised

21 study comparing the jubilee

22 dressing method to a standard

23 adhesive dressing for total

24 hip and knee replacements",

25 authored by Neil G. Burke and

others.

1 Exhibit 23 Email chain between410
2 Mark Albrecht and Mike Reed,
3 "Full workup of stats you
4 requested", dated 29 November,
5 2011.

6 Exhibit 24 Email from Mark416
7 Albrecht to Scott Augustine,
8 with attachment, dated
9 11/22/2015, Bates stamped
10 Albrecht_0002079-0002086

11 Exhibit 25 Anesthesia & Analgesia445
12 document entitled "Patient
13 Warming Excess Heat: Effects
14 on OR Ventilation Performance
15 During Total Knee
16 Replacement", Bates stamped
17 Belani_000002-000039

18 Exhibit 26 Email from Mark454
19 Albrecht to Paul McGovern and
20 others, "Fwd: A&A Decision for
21 MS#: AA-D-11-01334", dated 25
22 October 2011

23 Exhibit 27 Email chain between455
24 Mark ALbrecht, Mike Reed and
25 others, "Fwd: A&A DEcision for
MS#: AA-D-11-01334R1", dated
11 January 2012.

Exhibit 28 Spreadsheet, Bates461
stamped
AUGUSTINE_0005193-0005487

Exhibit 29 Printout of spreadsheet463
data

Exhibit 30 Screenshots of FAW v500
CWB YouTube video

DR. PAUL MCGOVERN

PROCEEDINGS

THE VIDEOGRAPHER: This is Day 2 of the deposition
of Dr. Paul McGovern. The deposition started yesterday
4 January, today is 5 January 2017, and it is 9:24 a.m.
This is the beginning of DVD 1 in volume 2 of Dr. McGovern's
deposition. Everybody who was in the room yesterday is here
today.

Can I remind the witness he was sworn in
yesterday and is still under oath. Can you --

THE WITNESS: Yes.

THE VIDEOGRAPHER: You're on the record, counsel.
It is 25 past 9.

EXAMINATION BY MR. SACCHET:

BY MR. SACCHET:

Q. Good morning, Dr. McGovern.

A. Good morning.

Q. As I mentioned yesterday, my name is Mr. Sacchet,
and I represent the plaintiffs 3M. Yesterday my learned
friend on the other side reviewed some of the ground rules
for the deposition. I'm going to go through few more today,
just to make sure we're on the same page with respect to the
procedures for our conversation. As you know, I'll be
asking you questions under oath and you'll be responding to
them. If at any time you don't understand a question or if

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you don't hear the question, please let me know, okay?

A. Yes.

Q. As was mentioned yesterday, it's best for the
record and the court reporter, if I ask a question, that you
let me finish asking the question before you answer, and
I'll do the same with respect to you in refraining from
asking a question before you've finished your answer.
Please provide audible "Yes" or "No" answers with respect to
the questions as opposed to a nodding or shaking of the
head. Is that agreeable?

A. Yes.

Q. And if at any time you need a break, just let me
know, and I'll find an appropriate spot to pause.

A. Sure.

Q. Before we jump into your background, with respect
to your educational and professional history, just a few
preliminary items. You've never met me before, have you?

A. Not before yesterday, no.

Q. And prior to yesterday, you'd never spoken to me
before, be it via e-mail or phone?

A. That is correct.

Q. You've never spoken to any members of the
plaintiff's counsel in this matter, have you?

A. That is correct.

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Q. Have you ever spoken to anyone on the side of the
defense, prior to yesterday?

A. I'd received communications from various people on
the side of the defense. I have only communicated with them
through my lawyers.

Q. Okay. Do you recall who those individuals were
that attended the --

A. Stephen Llewellyn, from Faeger Baker Daniels.
I received a LinkedIn message from a lawyer in the United
States, but I don't remember their name.

Q. Do you recall the content of the message?

A. It was similar to the initial contact from Stephen
Llewellyn, saying that 3M would like to depose me, and
asking me to get back in touch to arrange that.

Q. And did you get back in touch to arrange that?

A. I did not reply to the LinkedIn message at all, and
I replied to Stephen Llewellyn through my lawyers when
I arranged legal representation.

Q. Okay. So other than contact via your attorney,
you've had no personal contact with anyone on the other
side?

A. That is correct.

Q. I know you spoke a little bit yesterday about your
background as well, and I'm going to review some of that

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A. Thank you.

Q. This is a initial e-mail from Mr. Albrecht to yourself on May 19, 2011; correct?

A. Yes.

Q. He says, "See reviewer's comments below (only minor)."

A. Yes.

Q. Below that is an e-mail from -- actually a letter from James Scott, an editor of the journal?

A. Yes.

Q. To Mr. Albrecht?

A. Yes.

Q. It says:

"Thank you for submitting your paper for consideration by the Journal of Bone and Joint Surgery. It has been reviewed by experts in the field and by members of the editorial staff";

Does it not?

A. It does.

Q. On the third page of this e-mail there are comments from reviewer 2, correct? Which is designated on the second page but carrying over on to the third page?

A. Correct.

Q. In the first full paragraph, the reviewer states:

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"The second part of the paper is a study of the infection in the cases done in their unit over a period of years before, during and after the transition from the forced-air warming apparatus to the conductive material heating apparatus."

Do you see that?

A. I do.

Q. The reviewer goes on to state:

"This demonstrates that there were actual changes in infection rates which would fit well with the experimental data and therefore support the contention that there is a serious issue to be addressed with some of the warming devices."

Do you see that?

A. I do.

Q. Does that refresh your recollection that one of the editors of the Journal of Bone and Joint Surgery said that the study supported serious issues with respect to warming devices?

A. One of the peer reviewers said that.

Q. One of the peer reviewers?

A. Yes.

Q. Yesterday you were asked about some of the potential limitations of the study; correct?

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A. Yes.

Q. You were asked about particular patient demographics?

A. Yes.

Q. And table 1 of the study itself shows that some patient-specific demographics were similar between the patient groups who received forced-air warming versus conductive fabric warming; correct?

A. Yes.

Q. And table 2 shows that, as to those particular patient-specific demographics, including age, diabetes and length of pre-operative stay, that they did not significantly impact infection rates; correct?

A. That is what I understand from this data.

Q. With regard to other potential patient-specific demographics, including things like obesity, or incontinence, or fitness for surgery, do you have any reason to doubt that the two patient groups between forced-air warming and conductive fabric warming were different?

A. No.

Q. This data was observational in nature; right?

A. Correct.

Q. Observational data is a legitimate scientific methodology; correct?

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MR. C. GORDON: Object to the form of the question.

A. It is -- well, data is not a methodology.

BY MR. SACCHET:

Q. Studies.

A. But observational studies are legitimate scientific studies, in my opinion.

Q. In the absence of a randomized controlled study, observational studies are considered to be the next best alternative; correct?

A. I wouldn't know if they were the next best alternative, but they are a valuable component of the total body of knowledge on a subject.

Q. Are you aware that in other healthcare circumstances, such as the use of tobacco and cancer rates, that for a very long period of time there was never a randomized controlled trial that proved causation between the use of tobacco and cancer?

A. Absolutely, yes.

Q. And all that there was to rely on for many, many years, were observational studies?

A. Absolutely, yes.

Q. And we all know, beyond peradventure, that tobacco causes cancer?

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A. Yes.

Q. In order to conduct a randomized controlled trial with respect to infection rates in orthopedic procedures, you'd need a huge amount of funding, wouldn't you?

A. Yes.

Q. The patient population would have to be massive for it to be sufficiently powered?

A. Yes.

Q. Those two factors would make it difficult for a lot of scientists to conduct a randomized controlled trial on the rates of infection in joints between the use of a forced-air warming device and a conductive fabric warming device; correct?

A. Yes, amongst others.

Q. In fact, there is no study to this day that's a randomized controlled trial. I'll strike that.

So, despite the fact that a randomized controlled trial has not been conducted, this observational data is valuable?

A. Yes, I believe this observational data is valuable.

Q. You were also asked yesterday about the change in antibiotic protocol, were you not?

A. Yes.

Q. And we now know, through our conversation, that the

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period of data that was collected for this study began on July 1, 2008; correct?

A. Yes.

Q. And there was a transition in the middle between forced-air warming to conductive fabric warming; correct?

A. Yes.

Q. Okay. If we can turn to page 1540 of exhibit 13, there is a column on the left-hand side entitled "Joint infection data"; do you see that?

A. I do.

Q. Do you see where it states, kind of in the middle of that large paragraph:

"From July 2008 to February 2009, a single dose of gentamicin 4.5 mg/kg was advantage given at induction."

A. I do.

Q. "In March 2009 this was changed to teicoplanin 400 mg and gentamicin 3 mg/kg."

Do you see that?

A. Yes.

Q. So, in other words, gentamicin was applied during the forced-air warming period from July 1 to the end of February 2009, and then there was a combination of gentamicin and teicoplanin administered thereafter; correct?

A. For -- yes, there was, yeah.

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Q. For the purposes of our conversation, let's refer to the administration of only gentamicin as protocol 1; okay?

A. Okay.

Q. And let's refer to the combination of gentamicin and teicoplanin as protocol 2, okay?

A. Okay.

Q. Assuming the change in protocols did not affect deep joint infection rates between the warming devices, would you consider the change in antibiotic to be a confounding variable?

MR. C. GORDON: Object to the form of the question: incomplete hypothetical, assumes facts not in evidence.

A. I can't comment on that. I can't predict what the outcome would be, given an assumption which hasn't been tested.

BY MR. SACCHET:

Q. But if there was no difference in infection rates between the use of protocol 1 and 2, how could it be a confounding variable?

A. If there was no difference in infections caused by protocol -- infections in the situation of protocol 1 and protocol 2, then there was no difference in the infections

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between protocol 1 and protocol 2. But that's --

Q. A change in antibiotic protocol would not be a confounding factor with respect to infection rates? (Reporter clarification.)

A. If the change in antibiotic protocol made no difference to infections, then the change in antibiotic protocol would make no difference to infection rates.

Q. And let's say, with respect to protocol 2, that there is actually an increase in infections between those who received the same warming therapy versus those who received protocol 1.

A. Right.

Q. Would the change to protocol 2 be the reason for increased infections?

MR. C. GORDON: Same objections.

A. I don't know. The hypothetical, 'what would happen if this antibiotic had an affect' question, is not something that I can unpick and predict in terms of what did happen or what would happen. I don't feel able to comment on what would happen if a -- if part of this data were different or were removed from this, because the -- a confounding variable is so complex, and the influence that a confounding variable has is so complex, that I don't think it is possible for me to predict what would happen if

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1 DR. PAUL MCGOVERN
2 a potentially confounding variable were altered.
3 BY MR. SACCHET:
4 Q. Let's look at a document that might help you.
5 (Exhibit 19 marked for identification)
6 A. Thank you.
7 Q. Could you turn to the very last page of this
8 document. Do you see a table with four rows?
9 A. Yes.
10 Q. Have you seen this table before?
11 A. Not to my recollection.
12 Q. Do you recall being on a string of e-mails in which
13 you received an attachment called "McGovern data redone"?
14 A. Yes.
15 Q. That's on the third page of this e-mail thread?
16 A. Yes.
17 Q. Does the final page of this set of documents look
18 like it involves data?
19 A. It looks like it contains numbers which could be
20 data.
21 Q. And the first row is entitled "Ab Protocol 1/Forced
22 Air"?
23 A. Yes.
24 Q. Could that mean antibiotic protocol 1 forced air?
25 A. I can't speculate on what this might mean.

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1 DR. PAUL MCGOVERN
2 Q. Assuming that means antibiotic protocol 2 forced
3 air, what is the number of those developing an infection?
4 MR. C. GORDON: Same objection.
5 A. The number written in the table in front of me is
6 21.
7 BY MR. SACCHET:
8 Q. And what is the percent of those individuals
9 developing an infection?
10 A. The number in parenthesis next to "21" is "3.1".
11 Q. What is the P value on the far right-hand side with
12 respect to this row of data?
13 A. The number on the right-hand side of the first row
14 of this table labeled "P value" is 0.839.
15 Q. That figure is not a statistically significant
16 P value; correct?
17 A. It's, at the moment, just number in a table which
18 I have not seen before and can't interpret. So I can't say
19 anything is statistically significant or not, because I
20 don't know to what the data refers, and I'm not familiar
21 with the data. So I cannot say whether this is
22 statistically significant or not because the data, to me,
23 doesn't mean anything at the moment.
24 Q. Okay, fair enough. Assuming that there were --
25 assuming that the change in antibiotic was not a confounding

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1 DR. PAUL MCGOVERN
2 Q. Okay. Assuming that it means antibiotic protocol 1
3 forced-air warming, what is the percent of infections
4 labeled therein?
5 MR. C. GORDON: Object to the form of the
6 question: lack of foundation, assumes facts not in evidence.
7 A. The number on that row under "No.(%) Developing
8 Infection" is 11.
9 BY MR. SACCHET:
10 Q. And the parenthetical next to it is numbered what?
11 A. 2.8.
12 Q. And above that, in the dark blue column, there is a
13 parenthesis bearing a percent mark; correct?
14 A. Yes.
15 Q. And the title of that column is "Number developing
16 an infection"; correct?
17 A. Yes.
18 Q. So the parenthetical notation of "2.8" means 2.8
19 percent developing an infection; correct?
20 MR. C. GORDON: Same objection.
21 A. That is what this number appears to show, from my
22 reading of this table.
23 Q. And the next line is "Ab Protocol 2/Forced Air"; do
24 you see that?
25 A. I do see that.

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1 DR. PAUL MCGOVERN
2 variable ...
3 A. Right.
4 Q. ... would there be any reason to deselect patients
5 from the population presented in this study for those who
6 received a different type of antibiotic than others?
7 A. No, I --
8 MR. C. GORDON: Object to the form of question:
9 lack of foundation, assumes facts not in evidence,
10 incomplete hypothetical.
11 A. No, I think that it is not necessary in this case
12 to exclude patients receiving different antibiotic
13 prophylaxis regimens from the study, because that change has
14 been declared in the study. It is for the peer reviewer
15 and, ultimately, the reader, to decide if that confounding
16 factor significantly affects the data and how to interpret
17 that data. But the point in this instance, in my opinion,
18 is that this is an observational study, and what was
19 observed was declared and presented clearly. And so, in
20 that case, to the best efforts of the authors of this paper,
21 what has happened has been reported, and the results that
22 have been noted have been reported. And so, that being the
23 case, I think it is appropriate that the data which was
24 presented was presented in the way that it was.
25 BY MR. SACCHET:

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in jubilee dressing that occurred during the time in which
the data was collected for the McGovern study impacted
infection rates?

MR. C. GORDON: Object to the form of the
question: lack of foundation, incomplete hypothetical.

A. It's not possible to say, in my opinion. The
numbers in this study are too small. You have a number of
patients that is 124, and the numbers are too small to be
able to draw a meaningful conclusion in terms of infection,
with regard to these two variables, in my opinion.

BY MR. SACCHET:

Q. So if I could point out, to the extent that this
would change your mind, the asterisks which are denoted in
the right-hand column of the standard adhesive dressing
column; do you see those?

A. Yes.

Q. And a single asterisk stands for a P value of less
than 0.05; correct?

A. Mm-hm, yes.

Q. And a double asterisk stands for a P value of 0.01
and less?

A. Yes.

Q. And three asterisks stands for a P value of 0.001
or less; correct?

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A. Yes.

Q. The infection row has no such asterisk in it,
does it?

A. That's correct.

Q. So, because we established earlier that statistical
significance begins at 0.05, which is a single asterisk ...

A. Right.

Q. ... presumably this 0 percent infection rate, the
difference between 0 and 0 is non-significant; correct?

A. No, that's not how I would interpret this. There
is no data to draw a meaningful conclusion from. You need
to have some data, by my understanding, to be able to draw
a conclusion of statistical significance. You can't comment
on whether these data are statistically significant. If one
were designing this study purely to look at infection rates
between the two dressings, it is likely that the study would
need to include more patients and the study -- and to ensure
it was sufficiently powered to be able -- "powered" meaning
to have enough patients in it -- to see enough infections to
be able to draw a meaningful conclusion.

The fact that there were no infections in 124
patients is not surprising, because infection rates are
generally low. This is a problem of research in this
area. Because infection is rare, thankfully, you need

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large numbers of patients in studies to see if one
intervention has a difference with another
intervention, in terms of infection rates. In my
opinion, this study does not demonstrate superiority of
one adhesive dressing over another, purely in terms of
infection.

Q. Fair enough --

A. It may for other conditions, such as blistering and
leakage, but for infection -- because those are more
common -- consequences post-operation, and the study appears
to have been adequately powered to identify those
differences and state statistical significance. But for
infection, there were not enough incidences of infection to
be able to draw meaningful conclusions, or a difference
between the two.

Q. Are you aware of any paper that is adequately
powered that shows that a change from a standard adhesive
dressing to a jubilee dressing would statistically
significant -- significantly alter infection rates among
arthroplasties?

A. I am not aware of any such paper.

Q. Are you aware of any published papers that
suggest -- I should say that find statistically significant
differences between joint infection rates from the use of

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MSSA screening versus non-screening?

A. Sorry, could you say that again, please?

Q. Are you aware of any evidence that is statistically
significant that suggests that the use of MSSA screening
significantly impacts the rate of deep joint infections
among patients?

A. I'm not aware of any such papers.

Q. Are you aware of any evidence that pre-warming,
when used in combination with intraoperative warming,
significantly impacts deep joint infection rates among
patients?

A. I am not aware of papers which provide evidence of
that.

Q. Have you seen an article by Mr. Reed and another
individual, bearing the last name Refaie, which analyzed the
NHS SSI bundle?

A. I presume you mean Northumbria Foundation Trust.
I am aware that Mr. Reed and Mr. Refaie have done research
together. I may have seen such paper but I don't remember.

Q. Do you recall Mr. Reed, in that paper, making the
statement: "A switch to the alternative conductive fabric
warming led to a significant decrease in deep joint
infections"?

A. I -- that statement sounds familiar but I don't

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1 DR. PAUL MCGOVERN
 2 remember reading it in a paper.
 3 Q. Would you have any reason to doubt, if Mr. Reed
 4 made such a statement, the accuracy of such a statement?
 5 MR. C. GORDON: Object to the form of the
 6 question: lack of foundation, assumes facts not in evidence.
 7 A. If Mr. Reed indeed made that statement in a paper,
 8 I'd have no reason to doubt the veracity of that statement.
 9 BY MR. SACCHET:
 10 Q. Are you aware of the fact that after the McGovern
 11 paper was published in the Journal of Bone and Joint
 12 Surgery, that additional data supported an elevated
 13 odds-risk ratio?
 14 MR. C. GORDON: Object to the form of the
 15 question: assumes facts not in evidence, incomplete
 16 hypothetical.
 17 A. I was not.
 18 BY MR. SACCHET:
 19 Q. Okay.
 20 (Exhibit 23 marked for identification)
 21 Q. That's an e-mail entitled "Full workup of the stats
 22 you requested"; correct?
 23 A. Yes.
 24 Q. And there is an e-mail from Mr. Albrecht to
 25 Mr. Reed, and you are cc'd on the e-mail on November 29,

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 2 2011; correct?
 3 A. Yes.
 4 Q. And there is an attachment called "Results";
 5 correct?
 6 A. Yes.
 7 Q. And if you turn the page, there is a table. Does
 8 this table resemble the table in the published McGovern
 9 study?
 10 A. It does resemble it. I'll check if it is the same.
 11 Q. There are different data points, but just in terms
 12 of the style and form of the table?
 13 A. Err ...
 14 Q. It is exhibit 13, to make sure you're on the right
 15 one.
 16 A. I'm there. I'm on exhibit 13. Which table are you
 17 referring to? Table 1 in exhibit 13?
 18 Q. I am looking at -- yes. No.
 19 A. Table 2.
 20 Q. Yeah, the lower half of Table 2. I mean with parts
 21 of the lower half, as well.
 22 A. Yes, I would agree this is similar in form to part
 23 of Table 2 in what you refer as to the "McGovern paper".
 24 Q. Okay. And if we look at that table in the e-mail
 25 thread, for a conductive fabric, number developing

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1 DR. PAUL MCGOVERN
 2 infection, 7; correct?
 3 A. Oh, yes.
 4 Q. Number not developing infection, 792; correct?
 5 A. Yes.
 6 Q. For a total population of 709 patients who received
 7 conductive fabric warming; correct?
 8 A. Yes.
 9 Q. That number is significantly larger than the total
 10 population of individuals who received conductive fabric
 11 warming in the final published paper, exhibit 13; correct?
 12 A. That number is larger. To say it was significantly
 13 larger would require a statistically significant test. So
 14 be careful about using the words "statistically
 15 significantly", but it is a larger number.
 16 Q. How about double?
 17 A. Let's see. Conductive fabric 792 versus 368. Yes,
 18 I think that's a reasonable thing to say.
 19 Q. Okay. And if we go back to the text of the e-mail,
 20 Mr. Reed writes back to Mr. Albrecht and copies you in and
 21 says, in the last line of the first paragraph:
 22 "You are 3.6 times more likely to get an
 23 infection on FAW than CFW."
 24 Do you see that?
 25 A. Yes. It phrases a question, but yes.

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 2 Q. Yes. Do you have any reason to doubt Mr. Reed's
 3 statement to that effect?
 4 A. It appears that Mr. Reed is asking if that is what
 5 the data is showing in this table.
 6 Q. And do you see, in the table itself, a demarcation
 7 of 3.6 on the right-hand side of the odds ratio?
 8 A. I do.
 9 Q. So in fact Mr. Reed was referring to this table;
 10 correct?
 11 A. That is -- seems likely.
 12 Q. And this table was sent as a results attachment
 13 from Mr. Albrecht?
 14 A. Yes.
 15 Q. You have no reason to doubt Mr. Albrecht's ability
 16 to conduct statistical analysis of data, do you?
 17 A. None whatsoever.
 18 Q. You have no reason to doubt that, based on this
 19 patient population of those who received conductive fabric
 20 warming, which is double the size of the patient population
 21 in the McGovern study, that there was a 3.6 odds ratio?
 22 A. That is what this data appears -- (overspeaking) --
 23 MR. C. GORDON: Object to the form of the
 24 question.
 25 THE COURT REPORTER: Sorry, can you repeat the

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 2 objection, please.
 3 MR. C. GORDON: Form.
 4 A. That is what this data appears to show.
 5 BY MR. SACCHET:
 6 Q. So this data shows there is a 3.6 times increase in
 7 infection as a result of using forced-air warming devices
 8 compared to conductive fabric warming devices; correct?
 9 A. That is what --
 10 MR. C. GORDON: Object to the form of the
 11 question.
 12 A. That is what this table appears to show.
 13 BY MR. SACCHET:
 14 Q. And both this odds ratio and the odds ratio
 15 presented in the final published McGovern study are both
 16 above 3.0; correct?
 17 A. Yes.
 18 Q. So, based on this data in the increased patient
 19 population of those who received conductive fabric warming,
 20 this data corroborates the fact that there is at least
 21 a three times more likely chance that patients who received
 22 forced-air warming developed an infection, compared to those
 23 who received conductive fabric warming?
 24 MR. C. GORDON: Object to the form of the
 25 question.

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 2 (Break taken.)
 3 (3:04 p.m.)
 4 THE VIDEOGRAPHER: Back on the record at four
 5 minutes past three.
 6 (Exhibit 24 marked for identification)
 7 BY MR. SACCHET:
 8 Q. Mr. McGovern, are you aware of any data that's been
 9 collected regarding other healthcare facilities that have
 10 shown a decreased rate of infection after the switch from
 11 forced-air warming devices to conductive fabric warming
 12 devices?
 13 A. I am not.
 14 Q. If you could take a look at the exhibit which was
 15 just marked. The first page is an e-mail; is that correct?
 16 A. Yes.
 17 Q. From Mr. Albrecht to Scott Augustine, bearing the
 18 subject line "Results" with attachments "MA_edits"; correct?
 19 A. Yes.
 20 Q. And Mark Albrecht states:
 21 "I've updated the statistics in the white
 22 paper under **MA_edits.doc**."
 23 A. Yes.
 24 Q. "The updates include:
 25 "The statistics in the Table for all centers and

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 2 A. This data -- I can't agree with the term
 3 "corroborates the fact". The fact is not --
 4 BY MR. SACCHET:
 5 Q. Also shows?
 6 A. Yeah. Could you just repeat the phrase, please, or
 7 rephrase that? Or --
 8 Q. I'll rephrase the question.
 9 Based on the data presented in this table and the
 10 data presented in the McGovern study, both studies for
 11 both datasets show that there was a three -- at least
 12 a three times more likely chance that a patient
 13 developed an infection after using forced-air warming
 14 than conductive fabric warming?
 15 MR. C. GORDON: Object to the form of the
 16 question.
 17 A. Yes. Patients who were in the group with
 18 forced-air warming on this data appear to have had a three
 19 times or more higher incidence of infection compared to the
 20 conductive fabric group of patients for this study.
 21 THE COURT REPORTER: Can I just ask you to stop
 22 for 30 seconds, sorry.
 23 THE VIDEOGRAPHER: Going off at two minutes past
 24 three.
 25 (3:02 p.m.)

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 2 the pooled result[s]
 3 "The statistics in the discussion for the updated
 4 McGovern numbers provided as provided [sic] in the
 5 text."
 6 Do you see that?
 7 A. Yes.
 8 Q. In the third paragraph it says:
 9 "I think this is the best modeling approach
 10 (i.e. a conservative one) for the data you have,
 11 especially if you expect these results to be critically
 12 questioned down the road."
 13 Do you see that?
 14 A. Yes.
 15 Q. Okay. And the next page is a document entitled
 16 "Forced-air warming link to periprosthetic total joint
 17 replacement infections"; correct?
 18 A. Yes.
 19 Q. And the "Methods" says:
 20 "To investigate whether the rising
 21 contaminants from the waste FAW heat are linked to
 22 PJIs, we retrospectively collected joint implant
 23 infection data from three hospitals. We compared PJI
 24 rates during a period of forced-air warming to PJI
 25 rates during a period of free-air conductive fabric

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 2 warming. Surgical and antibiotic protocols were held
 3 constant."
 4 Do you see that?
 5 A. I see that.
 6 MR. C. GORDON: I'm going to object on foundation
 7 grounds to any questions about this, unless it is
 8 established that he did in fact write it, as it indicates on
 9 it.
 10 MR. SACCHET: My questions won't pertain to
 11 Mr. McGovern's contribution to this study or not.
 12 BY MR. SACCHET:
 13 Q. This document was attached to the e-mail from
 14 Mr. Albrecht to Mr. Augustine; correct?
 15 MR. C. GORDON: Objection: lack of foundation.
 16 A. There's no way for me to know if that's the case.
 17 BY MR. SACCHET:
 18 Q. Do the Bates numbers in the bottom right-hand
 19 corner follow one another?
 20 A. They are sequential numbers, yes.
 21 Q. Assuming that this document was attached to the
 22 cover e-mail, does it appear that Mr. Albrecht analyzed the
 23 statistics presented in this document?
 24 MR. C. GORDON: Objection: lack of foundation.
 25 A. If these documents are indeed related, it would be

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 2 reasonable to assume that Mr. Albrecht is referring to this
 3 document, but I've no way of verifying if that's the case.
 4 BY MR. SACCHET:
 5 Q. And that's why I ask for the assumption.
 6 A. If we're assuming that, then we'll assume that.
 7 Q. And you have no reason to doubt Mr. Albrecht's
 8 ability to analyze data; correct?
 9 MR. C. GORDON: Same objection.
 10 A. That's correct.
 11 BY MR. SACCHET:
 12 Q. If we could turn to page 3 in the Results section,
 13 there is a table; do you see that?
 14 A. Yes.
 15 Q. And Center 1 says "Patient Warming Device" and
 16 under that there's "Conductive Fabric and Forced Air". Do
 17 you see that?
 18 A. I do.
 19 Q. And in the columns there are four labels: "No.(%)
 20 Developing Infection", "No.(%) Not Developing Infection",
 21 "Odds Ratio" and "P value"; do you see that?
 22 A. I see that.
 23 Q. For Center 1, in conductive fabric warming, based
 24 on this dataset, it appears that two persons developed an
 25 infection; correct?

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 2 MR. C. GORDON: Objection: lack of foundation.
 3 MR. SACCHET: I said based on this dataset.
 4 MR. C. GORDON: Same objection.
 5 A. I haven't read the results or methods of this
 6 paper, so at the moment all I can see is that a number 2 is
 7 next to a row heading "Patient Warming Device Conductive
 8 Fabric" in a cell whose column is "No. Developing
 9 Infection", but I don't know what this refers to because
 10 I don't recall ever seeing this before.
 11 BY MR. SACCHET:
 12 Q. And next to that, there is a number -- I should say
 13 underneath that, there is a number 6; do you see that?
 14 A. A number 6, yes. I see the number 6.
 15 Q. And it appears that that number 6 corresponds to
 16 the label "Forced air" and "No.(%) Developing Infection";
 17 correct?
 18 A. The number 6 is within the cells with those labels,
 19 yes.
 20 Q. So it appears, based on this table and the way that
 21 it has been formatted, that two patients who received
 22 conductive fabric developed an infection, whereas six
 23 patients who received forced-air warming developed an
 24 infection?
 25 MR. C. GORDON: Objection: lacks of foundation.

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 2 Also, this goes pretty far beyond the fact witness
 3 limitation.
 4 A. I can't make that statement because I have not read
 5 the rest of the paper, and I -- this doesn't -- numbers in a
 6 table does not let me say that patients have received one
 7 thing or another. I need more information to be able to
 8 make that statement.
 9 BY MR. SACCHET:
 10 Q. Okay, let's look at the page 4 in the "Discussion"
 11 section.
 12 A. Page 4 in the "Discussion" section. Okay.
 13 Q. The fourth paragraph, second line, says:
 14 "The FAW patients who received the first
 15 antibiotic were drop from the results. This left 677
 16 patients with 22 PJIs in the FAW group receiving the
 17 second antibiotic (3.2% PJI rate). Then 14 more months
 18 of CFW patients were added for a total of 1097 CFW
 19 patients, which included 10 PJIs, all of whom received
 20 the second antibiotic."
 21 A. That's what it says.
 22 Q. "These new data show that the PJI rates decreased
 23 72% when FAW was discontinued and CFW initiated," totaling
 24 1774 patients with a P value of 0.004.
 25 Do you see that?

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A. This says "0.0004", but I see that, yes.

Q. "This 72% reduction compares favorably with the previously reported 74% reduction, indicating that the switch in antibiotics was not a significant variable."

Do you see that?

A. I see that.

Q. If this data was presented by Mr. Albrecht, would you have any reason to doubt it?

MR. C. GORDON: Object to the form of the question. Also lack of foundation, incomplete hypothetical, and assumes facts not in evidence.

A. This data is not interpretable by me at the moment because I have not read the paper. Data in isolation doesn't mean anything to me, so I can't make any comment on that data.

BY MR. SACCHET:

Q. Fair enough. Based on what we reviewed, the data presented in your paper, the McGovern paper ...

A. Yes.

Q. ... and the follow-up data that we reviewed, which Mr. Reed had commented on ...

A. Yes.

Q. ... do you have any doubt that the study period analyzed in the McGovern study recorded a 3.8 odds risk

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ratio?

MR. C. GORDON: Object to the form of the question.

A. The study data reported that odds ratio.

BY MR. SACCHET:

Q. And that data shows that there is a 3.8 more likely chance of developing a deep joint infection from the use of forced-air warming, compared to conductive fabric warming?

A. It showed that the odds ratio for these patients in these circumstances for this data was 3.8. That's what that showed. It did not necessarily show there was a higher chance; it just showed that that is what happened.

MR. SACCHET: OK. Do we need a break, or are we okay? Why don't we take one now, because I'm going into a new section.

THE VIDEOGRAPHER: Going off the record at thirteen minutes past three.
(3:13 p.m.)

(Break taken.)

(3:21 p.m.)

THE VIDEOGRAPHER: Back on the record at twenty-one minutes past three.

BY MR. SACCHET:

Q. Mr. McGovern, we're going to transition to what has

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been previously marked as exhibit 8. And again, put essentially everything else to the side.

A. Okey dokey.

Q. Okay. Beyond the first page, the second page begins a copy of a study entitled "Forced-Air Warming Design: Evaluation of Intake Filtration, Internal Microbial Buildup, and Airborne Contamination Emissions."

MR. C. GORDON: What page are you on?

MR. SACCHET: I am on 275, internal Bates number 3MBH00107864. Exhibit 8.

MR. C. GORDON: The binder?

MR. SACCHET: No. This is my binder.

MR. C. GORDON: I'm sorry, which exhibit was it?

MR. SACCHET: Exhibit 8.

A. I can see that.

BY MR. SACCHET:

Q. This article was co-authored by Mr. Reed, Mr. Kimberger, yourself and Mr. Albrecht; correct?

A. Correct.

Q. And if we could turn to the "Methods" section of the paper, which is still on that same page.

A. Yes.

Q. There are a number of boldface and italicized headings?

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A. Yes.

Q. The second one says: "Intake Filter Efficiency".

A. Yes.

Q. On the next page there's one entitled "Intake Filter Performance in the Operating Theater"?

A. Yes.

Q. And the third is entitled "Generation of airborne Contamination"?

A. Yes.

Q. These were the three variables that you examined in this study; correct?

A. Yes.

Q. And you examined a Bair Hugger model 750; correct?

A. That is what I understand was examined in this study, yes.

Q. And if you refer to internal page 275, the right-hand column at the top says:

"Prior research has rated the intake filtration efficiency of legacy FAW devices (Bair Hugger 505) at 93.8% for a 'older' filter model in clinical use (200708C) and 61.3% for a 'newer' filter model (200708D) scheduled to replace the older filter in clinical use."

Correct?